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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,555	09/25/2000	Veronique M. Braud	SHP-PT059	9366

7590

12/18/2001

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EXAMINER

DECLoux, AMY M

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 12/18/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/555,555

Applicant(s)

Braud et al.

Examiner

DeCloux, Amy

Art Unit

1644



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 26, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-29 are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

DETAILED ACTION

Please Note: In an effort to enhance communication with our customers and reduce processing time, Group 1640 is running a Fax Response Pilot for Written Restriction Requirements. A dedicated Fax machine is in place to receive your responses. The Fax number is 703-308-4315. A Fax cover sheet is attached to this Office Action for your convenience. We encourage your participation in this Pilot Program. If you have any questions or suggestions, please contact Paula Hutzell, Supervisory Patent Examiner at paula.hutzell@uspto.gov or 703-308-4310. Thank you in advance for allowing us to enhance our customer service. Please limit the use of this dedicated Fax number to responses to Written Restrictions.

1. Applicant's submission of the instant application as a 371 is acknowledged, however Claim 1 does not provide a technical feature that is distinguished over the prior art, as evidenced by Braud et al. (Nature (1998), Volume 391, pages 795-799) who teach a method of identifying the presence of CD94/NKG2+ cells and T cells in a sample comprising contacting the sample with HLA-E under binding conditions and detecting binding of HLA-E to the cells, (see entire article including Figures 1 and 2). Therefore, the instant invention lacks Unity of Invention. (It is noted that the inventive entity is not identical to the authorship of said paper because there are additional authors absent in the inventive entity).
2. Restriction is required under 35 U.S.C. 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted. A restriction is required under 35 USC 121 and 372 between one of the following groups:

Group I. Claim 18, drawn to the embodiment of a nonhuman mammalian cell which expresses HLA-E at the cell surface by virtue of a nucleic acid encoding HLA-E integrated into the genome of the cell

and Claims 9-13, drawn to the embodiment of a method of modifying NK cell activity against a potential target cell, comprising expressing HLA-E at the target cell surface.

Group II. Claims 1-8 and 14-15, drawn to the embodiment of a method of identifying the presence of CD94/NKG2+ cells and T cells in a sample comprising contacting the sample with HLA-E under binding conditions and detecting binding of HLA-E to the cells, and said cells.

Group III. Claims 16-17, drawn to the embodiment of a method of therapy comprising introducing an effective quantity of CD94/NKG2+ cells into a patient.

Group IV. Claim 19, drawn to the embodiment of a non-human mammal comprising cells which express HLA-E at the cell surface by virtue of a nucleic acid encoding HLA-E integrated into the genome of the cell.

Group V. Claims 20-23, drawn to the embodiment of a method of testing a compound for biological activity, which method comprises determining whether the presence of the compound affects the binding of HLA-E to the cells, and compound thereof.

Group VI. Claims 24-29, drawn to the embodiment of a multimer of HLA-E.

3. The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

4. Groups I, IV and VI are unique products, being drawn to a cell, a transgenic animal and a multimer of HLA-E, respectively. They differ with respect to their structures and physicochemical properties and do not have the same technical feature.

5. Groups I, II, III and V are unique methods. They differ with respect to ingredients, process steps and endpoints to achieve different goals. Therefore, they do not have the same technical feature.

6. The product Groups VI and II/V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. In the present case, the product as claimed, the HLA-E multimer, can be used for immunopurification of peptides that bind to HLA-E, as well as in a method of identifying the presence of CD94/NKG2+ cells and T cells in a sample comprising contacting the sample with HLA-E under binding conditions and detecting binding of HLA-E to the cells or in a method of testing a compound for biological activity, which method comprises determining whether the presence of the compound affects the binding of HLA-E to the cells.

7. Because these inventions are distinct for the reasons given above and have

acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy DeCloux whose telephone number is (703) 306-5821. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 pm. a message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers **other than elections** related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located In Crystal Mall 1. The faxing of such papers must conform with the notice published In the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Amy DeCloux, Ph.D.
Patent Examiner
Group 1640, Technology Center 1600
December 10, 2001

David A. Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT ~~182~~ 1644